



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/555,467

09/11/2006

Cheung Hoi Yu

2055.043

7542

23405

7590

12/01/2010

HESLIN ROTHENBERG FARLEY & MESITI PC
5 COLUMBIA CIRCLE
ALBANY, NY 12203

EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

12/01/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/555,467	Applicant(s) YU ET AL.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-19 and 26-41 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,4,17-19 and 26-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/7/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response to the office action filed on September 15, 2010 has been considered and acknowledged.

Status of the Application

2. Claims 5-16 are pending under examination. Claims 1-2, 4, 17-19, 26-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. Claims 3, 20-25 are canceled. All arguments and amendment have been fully considered and deemed persuasive for the reasons that follow. The instant amendment recites new limitations in the independent claims which were not present in the previously examined claims. Now the scope of the claims is changed. Accordingly following new combination of prior art is applied to reject the claims. The action is made FINAL necessitated by amendment.

New Grounds of Rejection necessitated by Amendment

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peiris et al. (US 7,267,942) in view of Therianos et al. (US 2005/0089862A1).

Peiris et al. teach a method of claim 5, 10, for nucleic acid (RNA) detection comprising the steps of nucleic acid isolation followed by nucleic acid amplification using real time PCR (see col. 11, line 16-47, col. 34, line 49-64).

With regard to claim 6, Peiris et al. teach that the nucleic acid amplification comprises PCR (see col. 11, line 16-47).

With regard to claim 7, Peiris et al. teach that said real time PCR uses fluorescently labeled probes (see col. 11, line 23-47).

With regard to claim 8, Peiris et al. teach that the nucleic acid is cDNA (see col. 11, line 23-30).

With regard to claim 9, 13, Peiris et al. teach that the nucleic acid is SARS coronavirus cDNA (see col.14, line 30-67).

With regard to claim 11, Peiris et al. teach that the method further comprises obtaining RNA from the biological sample and converting the RNA to cDNA using reverse transcriptase (see col. 11, line 16-47).

With regard to claim 12, Peiris et al. teach that the steps amplification and real time PCR uses primers (see col.11, line 23-47).

With regard to claims 14-16, Peiris et al. teach that the primers and probes correspond to SEQ ID NO. 1 (see col. 14, line 44-58).

However, Peiris et al. did not specifically teach pre-amplification of said nucleic acid before performing said real-time PCR.

Therianos et al. teach a method for multiplex real-time quantitative PCR comprising a pre-amplification step before conducting real-time PCR and real-time PCR was done using the amplified product of the pre amplification (see page 2-3, paragraph 0018, page 4, paragraph 0029-0030).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method for detecting a nucleic acid of a pathogenic agent as taught by Peiris et al. with the step of pre-amplification as taught by Therianos et al. for the purpose of developing a simple and efficient method for detecting a pathogenic agent. One skilled in the art would have motivated to combine the references because the ordinary artisan would have a reasonable expectation of success that the combination would result in a simple, sensitive and efficient method because Therianos et al. explicitly taught that the pre-amplification method provides a high throughput approach that utilizes a minute amount of starting material and reaches single copy levels of efficacy (see page 2, paragraph 0015, 0017) and such a modification of the method would be obvious over the cited prior art.

Response to Arguments:

4. The rejection of claims 5-8, and 10-12 under 35 USC 102(b) as being anticipated by Ratge et al. is withdrawn herein in view of the amendment.

5. The rejection of claims 5-6, and 8-16 under 35 USC 102(e) as being anticipated by Peiris I is withdrawn herein in view of the amendment.
6. The rejection of claims 5-16 under 35 USC 102(e) as being anticipated by Peiris II is withdrawn herein in view of the amendment.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637